

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/627,896	CO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Phillip Gambel	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/20/04; 5/25/04.
2. ☒ The allowed claim(s) is/are 1-4 and 6-63.
3. ☒ The drawings filed on 7/26/02 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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**PHILLIP GAMBEL**  
 Phillip Gambel  
 Primary Examiner 5/25/04  
 Art Unit: 1644  
 TOL-37 CENTER 1600

### DETAILED ACTION

1. Applicant's amendment, filed 2/20/04 has been entered.  
Claims 1-3, 6, 10-12, 16-18, 20, 22 and 23 have been amended.  
Claims 27-62 have been added.

Claim 5 has been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to nonelected invention and/or species

### EXAMINER'S AMENDMENT

2. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.
3. Authorization for this Examiner's Amendment was given in a telephone interview with Stewart Mittler on May 25, 2004.
4. Amend claim 2, line 1, by replacing "immunotolerance" with:  
-- a lack of responsiveness to an antigen -- .
5. Amend claim 2, line 2, by replacing "cell, or the like" with:  
-- or cell -- .
6. Amend claim 2, last line, by replacing "antibody" with:  
-- immunoglobulin -- .
7. Cancel claim 5.
8. Amend claim 34, line 1, by replacing "immunotolerance" with:  
-- a lack of response to an antigen -- .
9. Amend claim 34, line 2, by replacing "cell, or the like" with:  
-- or cell -- .
10. Amend claim 61, line 1, by replacing "immunotolerance" with:  
-- a lack of response to an antigen -- .
11. Amend claim 61, line 2, by replacing "cell, or the like" with:  
-- or cell -- .

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12. Add the following claim 63.

-- Claim 63. A method of treating an individual having an inflammatory disorder comprising administering a therapeutically effective amount of the humanized immunoglobulin having binding specificity for B7-2, said immunoglobulin comprising:

- a) at least one antigen binding region of nonhuman origin, and
- b) a portion of an immunoglobulin heavy chain of human origin derived from the III2R (SEQ ID NOS: 25, 29) or a portion of an immunoglobulin light chain of human origin derived from the H2F (SEQ ID NOS: 26, 30) variable region, wherein the immunoglobulin is administered in a carrier, and the humanized antibody has a binding affinity of at least  $10^7$  M<sup>-1</sup>. --

### REASONS FOR ALLOWANCE

13. The following is an Examiner's Statement of Reasons for Allowance:

Upon reconsideration of applicant's arguments and amended claims, filed 2/20/04 as well as those set forth herein in the Examiner's Amendment, the previous rejection under 35 USC 112, first paragraph, has been withdrawn. As indicated previously, the claimed methods comprising the administration of the claimed B7-2-specific humanized immunoglobulins appear free of the prior art. Accordingly, the pending claims are deemed allowable.

14. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.

Primary Examiner

Technology Center 1600

May 25, 2004